K091952

5. PREMARKET NOTIFICATION [510(K)] SUMMARY

SEP 10 2010

Applicant:	Nfocus™ Neuromedical, Inc. 2191 E. Bayshore Road, Suite 100 Palo Alto, CA 94303 USA Tel: 415-640-3377 Fax: 650-813-1869
Date Prepared:	June 29, 2009
Contact Person:	Robert H. O'Holla Vice President, Regulatory
Proprietary Device Name:	Acta™ VESSEL OCCLUSION SYSTEM
Common Device Name:	Arterial Embolization Device (KRD)
Classification:	Class II, 21 CFR 870.3300, Product Code KRD
Legally marketed device to which your firm is claiming equivalence:	Amplatzer Vascular plug

Device Description:
The Acta™ Vessel Occlusion System (VOS) is provided sterile and is intended for one-time use. The implant is a self-expandable, ovoid shaped implant with delivery device. The implant is made from a double layer of Nitinol wire mesh which is secured at proximal and distal ends with platinum marker bands. The delivery device allows the implant to be delivered through commercially available catheters. Detachment of the implant from the delivery device is achieved by operator activation of the delivery handle.

Intended Use:
The Acta VOS is indicated for arterial and venous embolizations in the peripheral vasculature.

Technological Characteristics of the Device Compared to the Predicate Device:
The Acta VOS uses similar technology, has similar intended use, functions and method of operation as the predicate device.

	Acta VOS	Amplatzer Plug
Intended Use	The Acta VOS is indicated for arterial and venous embolizations in the peripheral vasculature.	Amplatzer vascular plug is indicated for arterial and venous embolizations in the peripheral vasculature.
Device Function	Creates a physical barrier to effect vascular occlusion	Creates a physical barrier to effect vascular occlusion
Implant Materials	Nitinol	Nitinol

	Acta VOS	Amplatzer Plug
Implant Shape	Ovoid	Cylindrical
Method of detachment from delivery system	Controlled detachment from catheter	Controlled detachment from catheter

Summary of Studies:

As per the guidance for Abbreviated 510(k)s and the applicable standards, performance, sterilization and biocompatibility testing will be conducted and the results of the testing will verify that the Acta VOS product and system requirements are met ensuring that the product design conforms to the user needs and intended uses.

The following tests have been or will be performed prior to commercialization:

Delivery System
- Dimensional
- Tensile Strength
- Corrosion Resistance
- Force to Deploy

Implant
- Dimensional
- Tensile Testing
- Recapture Force
- Radial Force
- Corrosion
- MRI Compatibility
- Radiopacity
- Fatigue

System
- Simulated Device Use

Conclusion:

NFocus Neuromedical considers the Acta VOS to be substantially equivalent to the legally marketed predicate device with respect to the device design, intended use, patient population and anatomical site. Any differences in technological characteristics between the Acta VOS and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nfocus Neuromedical
c/o Mr. Robert O'Holla
Vice President, Regulatory Affairs
2191 E. Bayshore Road, Suite 100
Palo Alto, CA 94303

SEP 10 2010

Re: K091952
Trade/Device Name: Acta Vessel Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: September 2, 2010
Received: September 3, 2010

Dear Mr. O'Holla:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

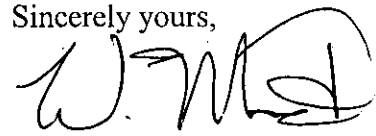
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATION FOR USE STATEMENT

510(K) Number (if known): K091952

SEP 10 2010

Device Name: Nfocus™ Neuromedical Acta™ Vessel Occlusion System

Indications for Use:

The Nfocus Neuromedical Acta Vessel Occlusion System (VOS) is indicated for arterial and venous embolizations in the peripheral vasculature specifically within the abdominal and thoracic cavities.

Prescription Use __X__ (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COINTNUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091952